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510(k) SUMMARY

1. **Submitted by:**

Hospira, Inc.
D-389, Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045
Attn: Diane Rennpferd

Phone: (224) 212-5452
Fax: (224) 212-5401

DEC 1 1 2006

2. **Date Prepared:** October 25, 2006

3. **Name/Classification of Device:** Fluid Delivery Tubing
Class II, 80-FPK, 21 CFR 880.5440

4. **Trade Name of Proposed Device:** LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Sets

5. **Predicate Devices:**

Device Name	510(k) Number
Dial-A-Flo®	PE
GraviTech™ Flow Controller Primary Set / GraviTech™ flow Controller Extension Set	K030467 (IV Medical Inc.)

6. **Proposed Device Description:**

The LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Set will consist of variations of the following components: non-DEHP plasticized polyvinyl tubing, piercing pins, fluid shut off devices, integral CLAVE® ports or prepierced injection sites, backcheck valves, semi-rigid adapters, male adapter and air filter assembly. The GraviTech™ device provides a manual flow control with head height compensation to the LifeShield® product line.

7. **Statement of Intended Use:**

The LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Sets are intended for use in controlling the infusion rate of I.V. fluids from a container to a patient's vascular system. The indications for use of the LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Sets include intravenous infusion where a manual flow control is desired.

8. **Summary of Technological Characteristics of New Device Compared to Predicate Devices:**

The LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Set as described in this submission is substantially equivalent to the predicate LifeShield® Latex-Free Regulator I.V. Dial-A-Flo® set family with respect to the following characteristics:

Similarities:

- Intended for the delivery of fluids from a container to a patient's vascular system.
- Provided with a sterile and non-pyrogenic fluid-path
- Intended for one-time use
- Technology and operating principles
- Method of sterilization
- Similar materials of construction
- Provides manual flow control

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Differences:

- The LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Sets will have head height compensation

The LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Set will meet the functional claims and intended use as described in the product labeling, and is as safe and effective in terms of substantial equivalence as the predicates LifeShield® Latex-Free Regulator I.V. Dial-A-Flo® set family and GraviTech™ Flow Controller Primary Set / GraviTech™ flow Controller Extension Set (cleared under K030467 to IV Medical Inc.)

The claim for substantial equivalence is supported by the information provided in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diane Rennpferd
Senior Associate, Global Regulatory Affairs Devices
Hospira, Incorporated
275 North Field Drive
Department 389, Building H2
Lake Forest, Illinois 60045

DEC 1 1 2006

Re: K063239
Trade/Device Name: LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administrative Set
Regulatory Class: II
Product Code: FPA, FPK
Dated: October 25, 2006
Received: October 26, 2006

Dear Ms. Rennpferd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

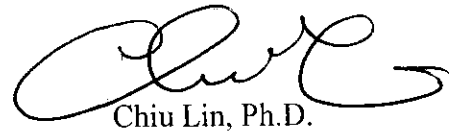
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K063239

Device Name: **LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Sets**

Indications for Use:

The LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Sets are intended for use in controlling the infusion rate of I.V. fluids from a container to a patient's vascular system. The indications for use of the LifeShield® Latex-Free GraviTech™ Flow Controller I.V. Sets include intravenous infusion where a manual flow control is desired.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

...Cardiology, General Hospit...
...Dental Devices

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